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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,175	05/24/2001	Thomas Tobin	434-226	3002

1009 7590 05/23/2003

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247 NORTH BROADWAY  
LEXINGTON, KY 40507

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/865,175	<b>Applicant(s)</b> TOBIN, THOMAS	
	<b>Examiner</b> Rebecca Cook	<b>Art Unit</b> 1614	

**-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20,22-36 and 38-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,22-36 and 38-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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The specification is objected to. Tables 1-3 contain graphs that should be deleted from the specification and resubmitted as drawings. A section titled "Brief Description of the Drawings" should be added to the specification. See MPEP 608.01 citing 37 CFR 1.58 "Chemical and mathematical formulae and tables" which recites that drawings may not be included in the specification.

Applicant's intent to amend the specification is noted.

The disclosure and claims are objected to because of the following: compounds "clonidine" and "atipamezole" appear to be misspelled.

Appropriate correction is required both in the specification and in the claims.

Claims 49-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a guanidine derivative that possesses the requisite .alpha. adrenergic receptor agonist activity, does not reasonably provide enablement for any and all guanidine derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On pages 11 and 12 it is emphasized that the guanidine derivative employed in the method must possess .alpha. adrenergic receptor agonist activity.

Claims 20, 22-36, 38-48, 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 20, 36, 50 the term chlonidine is confusing and it is not seen how it differs over clonidine. See the attached STN search which does not display any answers for "chlonidine."

In view of the amendment to claim 38 the earlier rejection under 35 U.S.C. 112, second paragraph is withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 22-36, 38-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,635,204, alone or in view of Veterinary Pharmacology and Therapeutics (Adams).

'204 (abstract, column 1, lines 35-47, column 2, lines 13-16) discloses a method of inducing sedation and analgesia using a guanidine derivative, including guanabenz and clonidine. It further discloses a method of reversing the analgesia and sedation using the instant .alpha.adrenergic antagonist. Claim 49 differs over '204 in reciting a method for providing chemical restraint. The claims further differ over the reference in requiring specific routes of administration, subjects and dosages. However, once a method or use is known it is within the scope of the artisan to determine optimum routes of administration, subjects and dosages. Additionally, Adams (page 160, column 2, "Tranquilizer-Sedatives" – page 161, column 1, lines 1-2) discloses that sedatives are used in animals to produce "chemical restraint."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP-1200/1614

May 21, 2003

Attachment

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DICTIONARY FILE UPDATES: 6 APR 2003 HIGHEST RN 501901-52-6

TSCA INFORMATION NOW CURRENT THROUGH MAY 20, 2002

Please note that search-term pricing does apply when  
conducting SmartSELECT searches.

Crossover limits have been increased. See HELP CROSSOVER for details.

Experimental and calculated property data are now available. See HELP  
PROPERTIES for more information. See STNote 27, Searching Properties  
in the CAS Registry File, for complete details:  
<http://www.cas.org/ONLINE/STN/STNOTES/stnotes27.pdf>

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L1 27 CLONIDINE  
  
=> s chlonidine  
0 CHLONIDINE  
L2 0 CHLONIDINE